

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

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C.A. No. 07-792 (GMS)

JURY TRIAL DEMANDED

**REPLY BRIEF IN SUPPORT OF MOTION TO TRANSFER IN
FAVOR OF PENDING FLORIDA JURISDICTION, OR IN THE
ALTERNATIVE STAY THE DELAWARE LITIGATION**

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This case should be transferred to Florida because it will proceed faster there than it can here. The Apotex parties will suffer actual prejudice if this case is not transferred to Florida because any delay in resolution of this litigation delays Apotex's ability to get its generic alfuzosin product to market. The public also will be prejudiced by any delay in resolution of this litigation, because it will be forced to pay Sanofi monopolistic prices for alfuzosin until Sanofi's patent is invalidated. By the same token, Sanofi stands to gain handsomely from these monopoly profits the longer it can delay the resolution of this litigation. Sanofi's arguments against transfer thus are motivated by a strong desire to prolong this litigation. Sanofi is one of the largest pharmaceutical companies in the world, with sales of over \$30 billion annually. Sanofi can afford to litigate this case anywhere in the world. All of Sanofi's arguments about convenience and preference for first filed actions are make-weight arguments that have no application in a Hatch-Waxman proceeding such as this, where the statute requires expeditious resolution, and the defendant and the public face actual prejudice from proceeding with one case over the other.

ARGUMENT

I. SANOFI'S ARGUMENTS IGNORE THE PUBLIC INTERESTS AND FOCUS ON EXTENDING THIS LITIGATION.

Sanofi's patent directed to a method for treating a prostate condition (dysuria) known to be treatable with alpha-adrenergic receptor blockers – with a known alpha-adrenergic receptor blocker (alfuzosin) is invalid. Sanofi's goal is to make this litigation drag out as long as possible so it can maximize its monopoly profits before it faces the inevitable reckoning day.

The Hatch-Waxman Act requires these cases to be decided quickly, and also requires the parties to cooperate in expediting the action. *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (noting Congress enacted the Hatch-Waxman Act to “get generic drugs into the hands of patients at reasonable prices – fast.”); 21 U.S.C. § 355 (j)(5)(B)(iii) (“In such an action, each of

the parties shall reasonably cooperate in expediting the action.”). Here, the public interests in affordable generic medicines is aligned with Apotex’s position and with transfer of this case to Florida. *See Jumara v. State Farm Inc. Co.* 55 F.3d 873, 879 (3d Cir. 1995).

The most expeditious way to resolve this litigation is to move the case down to Florida.¹ There is no dispute that the Florida case will be done at a time when this case is in its early stages. The Florida Court has entered a Scheduling Order setting a discovery schedule with discovery closing in August and a trial date in October 2008. (Dkt. 11 at Exhibit C). Discovery in Florida already is well underway – with initial disclosures already having been served, document production and interrogatory requests pending, and a motion for entry of a Protective Order already on file². Sanofi’s arguments attempting to discount the Florida Court’s Scheduling Order and seeking to convince this Court that the scope of discovery requires this matter to proceed on a slower track in Florida already were rejected by the Florida Court. On at least three separate occasions, the Florida Court was presented with and rejected Sanofi’s arguments about how complex the case is, seeking to extend discovery an additional 13 months (to April 2009) and the trial date (to September 2009). The Florida Court has stuck to its schedule with the close of discovery in August 2008, a dispositive motion deadline of August 2008 and a trial date of October 2008. Just days ago, on February 8, 2008, the Florida Court reiterated this schedule, expressly rejecting (again) Sanofi’s proposed extended schedule. *See Order Denying as Moot*

¹ On February 5, 2008, Sanofi moved pursuant to 28 U.S.C. §1407 to have the Judicial Panel on Multidistrict Litigation transfer all the alfuzosin cases to Delaware for consolidated or coordinated pretrial proceedings. Apotex will oppose consolidation. Apotex’s opposition is due February 25, 2008.

² Sanofi mentions that the Protective Order has not yet been entered in the Florida litigation, but this is only because Sanofi is opposing entry of any Protective Order in the case – even though Apotex’s proposed Protective Order is substantively identical to a Protective Order that Apotex’s and Sanofi’s same lawyers negotiated in another currently pending ANDA litigation.

Defendants' Motion for Extension of Time and Plaintiffs' Motion to File Scheduling Report, attached hereto as Exhibit A.

More amazingly, Sanofi contends that Apotex will need so much discovery in the Florida case that the case cannot possibly proceed to trial in October. When a plaintiff starts making arguments for its adversaries it is usually a good time to pause, reflect and question the merits of those arguments. Apotex is prepared to conduct the necessary discovery in the amount of time allotted by the Florida Court. The Florida Court, after considering Sanofi's arguments twice, is prepared to move forward with the litigation on the scheduled track. The only party not prepared here is Sanofi.

II. APOTEX HAS MET ITS BURDEN THAT THE CONVENIENCE OF THE PARTIES AND WITNESSES FAVORS TRANSFER

There is no connection to Delaware that would warrant denying a transfer to the more convenient forum of Florida. As stated in Apotex's opening brief, the only connection this matter has to Delaware is the incorporation of Apotex Corp. and Sanofi-Aventis U.S. (Dkt. 11 at 9). This is not enough to justify proceeding in a less convenient forum. *Mentor Graphics Corp. v. Quickturn Design Systems, Inc.*, 77 F. Supp. 2d 505, 509 n.6 (D. Del. 1999) ("Although the court does not mean to suggest that a defendant's state of incorporation is irrelevant to a venue transfer inquiry, certainly not dispositive.").

Sanofi does not dispute that there are no relevant witnesses or documents in Delaware. Rather, Sanofi argues that because Apotex has litigated in Delaware previously it should not be allowed to transfer a case to another jurisdiction. For example, Sanofi tries in vain to compare this case to *Alcon Mfg., Ltd. v. Apotex, Inc.*, No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026 (S.D. Ind. Mar. 14, 2007), where Apotex filed a motion to transfer venue from the Southern District of Indiana to the Southern District of Florida. However, *Alcon*, is readily distinguished.

Alcon, unlike Sanofi, did not sue Apotex in the Southern District of Florida. It only sued Apotex in Indiana. Thus, there was no case already pending in Florida. Also, notably, unlike the situation in *Alcon*, here, the Florida litigation already is well underway. In *Alcon*, the Florida case never got started.

Sanofi's argument that the interests of justice are best served by litigating this matter in Delaware with 13 other defendants is equally without merit. This proposed consolidation will only slow the adjudication process which is contrary to the public interests as outlined by the third circuit in *Jumara*. *Jumara*, 55 F.3d at 879. Sanofi's argument assumes that this action shares common questions of fact and law. As explained in Apotex's opening brief at 7-8, while there may be some overlap of invalidity arguments concerning the '491 patent, the noninfringement defenses under the '940 patent will be different (Apotex was not sued on the '940 patent because its proposed ANDA product is different from what is claimed in that patent (Sanofi has admitted this), and it is likely that Apotex's ANDA product is substantially different from the other 13 defendants who were sued for infringing the '940 patent). To the extent there is overlap of invalidity issues, the remaining Delaware cases will benefit from the work already done on those issues in Florida. And the rulings in Florida, while not binding, will be instructive and also will help to narrow if not resolve the issues remaining here to everyone's benefit.

The legal authority cited by Sanofi is not helpful to its position. For example, Sanofi attempts to compare this case with *Alere Medical, Inc. v. Health Hero Network, Inc.*, No. C-07-05054 CRB, 2007 WL 4351019 (N.D. Cal. Dec. 12, 2007) and *Tingley Systems, Inc. v. Bay State HMO Management, Inc.*, 833 F. Supp. 882 (M.D. Fla. 1993). However, neither *Alere* nor *Tingley* are anything like this case. Most significantly, both of the cases cited by Sanofi involve lawsuits where the two opposing parties raced to different courthouses to file suits against each other.

Unlike the situation in the two cited cases, this case involves keeping a case from being litigated in a more convenient and expedited jurisdiction and joining it in a lawsuit with different parties who are accused of infringing substantially different products. The only thing denying Apotex's transfer to Florida will accomplish is prolonging the adjudication of these issues.

III. SANOFI VOLUNTARILY CHOSE FLORIDA AS A FORUM AND CANNOT HIDE BEHIND THE FIRST FILED RULE TO DELAY THE LITIGATION PROCESS

Sanofi chose Florida as a forum to litigate this lawsuit. Sanofi's contention that this lawsuit was only filed as a protective measure because it feared the Delaware action would be dismissed for lack of personal jurisdiction is as irrelevant as it is untrue. Sanofi's assertion is untrue because Sanofi had 45 days in which to sue Apotex after receiving Apotex's Paragraph IV certification letter. If Sanofi really were concerned about jurisdiction in Delaware, it could have sued Apotex here anytime during the first 24 days of that 45 day period, and still had sufficient time to file suit in Florida after Apotex, Inc. answered, if Apotex, Inc. had challenged personal jurisdiction. In any event, the first-filed rule does not apply automatically, especially when a plaintiff chooses to file two identical lawsuits against the same party in two different venues. *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 489 (E.D. Va. 2005); *Employers Reins. Corp. v. MSK Ins., Ltd.*, No. Civ. 01-2608-CM, 2003 WL 21143105, at *6 (D. Kan. Mar. 31, 2003).

Sanofi incorrectly argues that the so-called "protective lawsuit" is now common in ANDA cases and that the first-filed case is to be preferred over the "protective" suit. (Dkt. 14 at 13-5). This argument is nonsense, flying in the face of the numerous cases that Apotex cited which say just the opposite. *See, e.g., Aventis*, 403 F. Supp. 2d at 489, 490 (E.D. Va. 2005) ("If the Maryland forum is in any way questionable in order to necessitate a "protective filing" as Plaintiffs maintain, then this Court is clearly the better forum, as all of the parties agree that both

jurisdiction and venue lie here.”); *Adams Resp. Therap. v. Mutual Pharm. Holdings*, No. 2:06-CV-04700-HAA-ES (D.N.J.) Dkt. No. 14, Nov. 16, 2006 Order at 2) (Dkt. 11 at Exhibit D); *Adams Resp. Therap. v. Mutual Pharm. Holdings*, No. 2:06-cv-04418-PD (E.D. Pa.), Dkt. No. 31, Nov. 2, 2006 (Order at 2) (Dkt. 11 at Exhibit E).

More importantly, this argument ignores the public and private interest factors applied by 28 U.S.C. §1404 and the Third Circuit, which here dictate that the case be transferred, as explained above. *Jumara v. State Farm Inc. Co.*, 55 F.3d 873, 879 (3d Cir. 1995); 28 U.S.C. § 1404.

Sanofi wrongly argues that *PDL Biopharma, Inc v. Sun Pharmaceutical Ind., Ltd.*, No. 07-11709, 2007 WL 2261386 (E.D. Mich. Aug. 6, 2007) and *Celgene Corp. v. Abrika Pharm., Inc.*, No. 06-5818-DSW, 2007 WL 1456156 (D.N.J. May 17, 2007), are factually identical to the present lawsuit. (Dkt. 14 at 15). Sanofi omits key factual differences in these cases. Unlike the case here, there was no scheduling order or early trial date set in the second-filed court in *PDL*. The *PDL* defendants had no evidence to support the argument that the litigation would be considerably more expedited in the second-filed district. In this case, the Florida Court has entered (and re-affirmed) a scheduling order with a trial date 9 months from now.

The facts in *Celgene* are even more inapposite to the instant situation. There, the Defendants did not make any contention that one forum was more convenient than the other. *Celgene*, 2007 WL 1456156 at *3. Further, the Defendants conceded that “there was no appreciable difference between this Court and the Delaware Court regarding the many public interest factors.” *Celgene*, 2007 WL 1456156 at *5. Here, Apotex has shown that both the convenience of the witnesses and parties and the public interests factors weigh heavily in favor of transfer to Florida.

None of the cases cited by Sanofi apply to the present situation where Plaintiff filed two identical lawsuits, the convenience of the parties and witnesses and the situs of material events weigh in favor of transferring the case in Florida and the expedited docket in Florida serve the interest of justice.

CONCLUSION

For the foregoing reasons, Sanofi's Delaware lawsuit against the Apotex defendants should be transferred to Florida or stayed in favor of the Florida litigation.

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Dated: February 11, 2008
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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Kenneth L. Dorsney, hereby certify that on February 11, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on February 11, 2008, the attached document was Electronically Mailed to the following person(s):

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EXHIBIT A

UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Miami Division

Case Number: 07-61800-CIV-MORENO

SANOFI-AVENTIS and SANOFI-AVENTIS
U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.

**ORDER DENYING AS MOOT DEFENDANTS' MOTION FOR EXTENSION OF TIME
AND PLAINTIFFS' MOTION TO FILE SCHEDULING REPORT**

THIS CAUSE came before the Court upon Defendants' Motion for Extension of Time to Comply with Requirements of Local Rule 16.1 or, in the Alternative to File Unilateral Scheduling Report and Proposed Scheduling Order (**D.E. No. 29**), filed on **January 31, 2008**, and Plaintiffs' Motion to File Scheduling Report and Proposed Scheduling Order (**D.E. No. 30**) filed on **February 1, 2008**.

THE COURT has considered the motions and the pertinent portions of the record, and being otherwise fully advised in the premises, it is

ADJUDGED that the motions are **DENIED** as moot as the Court issued a scheduling order in this case on **January 3, 2008**.

DONE AND ORDERED in Chambers at Miami, Florida, this 8th day of February, 2008.



FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record